

## :Session 1: Challenges and available solutions for aseptic techniques

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> Aseptic Processing Workshop July 2014; Indore

Connecting People, Science and Regulation

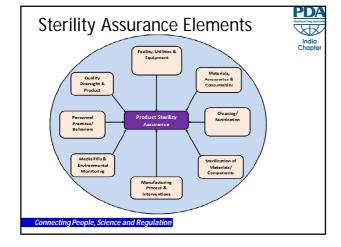
### Introduction



It is always the right time to talk about "Aseptic Processing and Techniques"  $\,$ 

- Aseptic processing requires high composure, perseverance, and performance to result in the highest degree of control and assurance.
- Aseptic processing always requires right attitude and critical thinking.
- No single tool is perfect in completely eliminating the risk of a non-sterile unit.
- > The challenges of aseptic process exist in every country and in every culture.

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## Perspective



Aseptic techniques and processes have always included the following:

- > The design of facilities, equipment and the process.
- Qualification of facilities/ equipment and aseptic process validations (media fills, smoke studies, etc.) including routine process controls.
- Environmental monitoring and controls during aseptic manufacturing.
- Personnel qualification and practices in aseptic core.

Based on my experience, there are other challenges unique to India.

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## Challenges

# Panatoral Drug Association India Chapter

#### **Aseptic Practices**

- · Cleanroom behavior outside the "cleanroom".
- Not just demonstrating proper techniques but operators need an in-depth understanding on purpose of the technique.
- Ability for operators to explain job functions.
- Culture that encourages open communication of the issues.

#### Consumables

- Critical or high risk consumables in aseptic area.
- Qualification of consumables before their use in aseptic manufacturing.
- Controls across the life cycle to assure and demonstrate these elements do not pose risk of product contamination.

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## Challenges



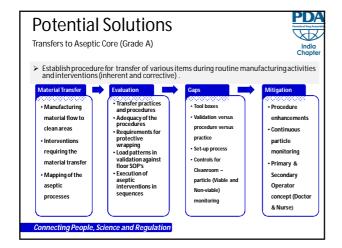
#### Media Fills, Smoke Studies and EM Program

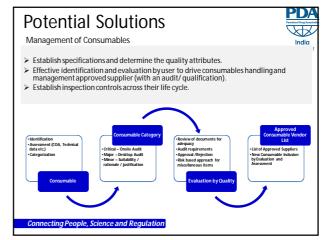
- Trending of interventions for aseptic process simulation.
- Ensure representative interventions are completed by operators.
- Smoke studies used to fullest extent.
- Meaningful environmental monitoring program.

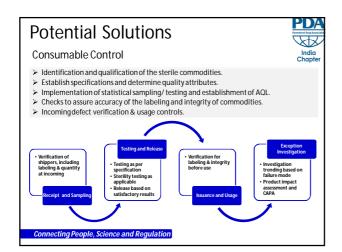
#### **Facility and Equipment Upgrades**

- Legacy aseptic equipment with minimum barrier systems.
- Retro fit barriers/ glove ports on legacy systems.
- · Facility maintenance.
- Power outages

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## **Potential Solutions**



#### Personnel Training

- > Best return on investment if done correctly.
- Leadership must support the time training will take and be prepared for how this time will impact operation schedules.
- Ultimately poor aseptic technique will result in a significant increase in costs.
- > Teach "Why" and not just "What".
- Open communication at all levels encourage discussion on errors and improves performance.
- Constant reinforcement on floor and not in office.
- > Perform "knowledge" audits of aseptic personnel.
- > Aseptic core monitoring program to close the loop.

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